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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,959	09/14/2005	Gregor John McLennan Anderson	ZGNX-115	6929

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EXAMINER	
LANDRY II, GERALD ERNEST	

ART UNIT	PAPER NUMBER
3763	

MAIL DATE	DELIVERY MODE
02/02/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/506,959	ANDERSON ET AL.	
	Examiner	Art Unit	
	GERALD LANDRY II	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 November 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-56* is/are pending in the application.

4a) Of the above claim(s) *1-30 and 32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31, 33-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 31 and 33-56 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,447,475 to Castellano.

Regarding claims 31 and 33-56, Castellano teaches a casing; a cartridge containing a medicament and an orifice at one end; a drive mechanism **(5029)** which upon actuation applies force to the medicament, forcing the medicament out of the orifice and through the patient's skin; a trigger mechanism **(5034, 5037)** which actuates the drive mechanism; a safety mechanism **(5026)** which, in a first configuration, prevents the trigger mechanism from actuating the drive mechanism and in a second configuration allows trigger mechanism to actuate the drive mechanism, wherein the casing encloses injector device components and incorporates an actuator mechanism which moves the safety mechanism from its first configuration into its second configuration **(column 20 line 62 – column 23 line 28)**; wherein the actuator mechanism comprises a portion extending outside of the casing which portion is accessible to a user and which when the portion is moved by the user the movement brings the safety mechanism into its

second configuration **(refer to marked-up figures below and columns 20-23)**; wherein the safety mechanism in its first configuration prevents the trigger mechanism from moving **(column 23 lines 21-24)**; wherein the actuator mechanism has a structure selected from the group consisting of a button **(refer to marked-up figures below)**, a tongue **(refer to marked-up figures below)** and a lever; wherein the actuator mechanism is comprised of a component **(5080)** which applies a pulling force to the safety mechanism to pull the safety mechanism from its first configuration into its second configuration **(column 23 lines 24-28; note: "a" pulling force)**; further comprising: a retaining mechanism **(5010)** which retains the safety mechanism of an enclosed injection device in its second configuration after the safety mechanism has been brought into its second configuration **(column 23 lines 21-24 denotes capability)**; wherein the safety mechanism comprises an obstructer portion **(spring; column 23)** which in the first configuration obstructs, and in the second configuration allows, movement of the trigger mechanism **(column 23)**; wherein the safety mechanism comprises a collar **(5026)** shaped to surround a portion of the injection device, the collar is moveable from its first collar configuration into its second collar configuration in a direction generally perpendicular to a direction in which the medicament exits the orifice, the collar comprising an obstructer portion **(column 23)**; wherein the trigger mechanism is comprised of two moveable upper and lower sleeve portions which on relative movement allow the drive mechanism to act, and the safety mechanism comprises an obstructer portion **(see above)** which in its first configuration obstructs, and in its second configuration allows, the relative movement of the sleeve portions **(refer to marked-up figures below)**; wherein the safety mechanism comprises an obstructer portion which is brought from its first configuration to its second configuration by a movement of the

obstructer portion in a direction perpendicular to a direction of relative movement of the two sleeve portions **(i.e. a spring, column 23 (also note that it is possible for the spring to expand radially))**; a casing which partially encloses a needleless injection device **(refer to marked-up figures below)**; a drive mechanism which forces medicament out of the orifice and through the patient's skin **(refer to marked-up figures below)**; a break-off tip **(5046)** which closes the cartridge orifice prior to being broken off; wherein the casing provides for a sequential operation of the needleless injection device **(refer to marked-up figures below)**; wherein the sequential operation provides for (a) breaking off the break-off tip; and (b) placing the safety mechanism in the second position **(refer to marked-up figures below and column 23)**; wherein breaking off the break-off tip exposes an actuator for the safety mechanism **(allows for actuation thus exposing the actuator)**; wherein the casing comprises moveable first and second casing components, a first casing component adapted to hold the injection device, and a second casing component adapted to bear upon the break-off tip as a result of relative motion of the first and second components to apply a force thereto causing the break-off tip to break off from an injection device enclosed within the casing **(capability shown in marked-up figures below)**; wherein the first casing component is elongated with an opening at a first end **(refer to marked-up figures below)**; wherein the first casing component is elongated along a longitudinal axis, and wherein the second casing component is designed to apply a rotary motion relative to the first portion so as to bear on the break-off tip of a container held by the first casing portion, and to apply a twisting shearing force to the frangible joint between the break-off tip and the container **(capability shown in the marked-up figures below)**; wherein the rotary motion is chosen from: transverse to the longitudinal axis; perpendicular to the longitudinal axis; coaxial

with the longitudinal axis; about a rotation axis parallel to but non-coaxial with the longitudinal axis; about a rotation axis at a non-zero angle to the longitudinal axis **(this can be accomplished by twisting the second casing component)**; wherein the rotary motion is about a rotation axis at a non-zero angle to the longitudinal axis **(capability shown in the marked-up figures below)**; wherein the second casing component comprises a cover portion **(5046)** over the actuator for the safety mechanism which prevents operation of the actuator for the safety mechanism until the cover portion is removed; wherein the drive mechanism comprises a compressed gas cylinder **(abstract; 5012)**; wherein the casing comprises a first casing sub-part and a second casing sub-part which fit together by a method chosen from, a tight friction fit, and a snap-fit fit **(capability shown in marked-up figures below)**.

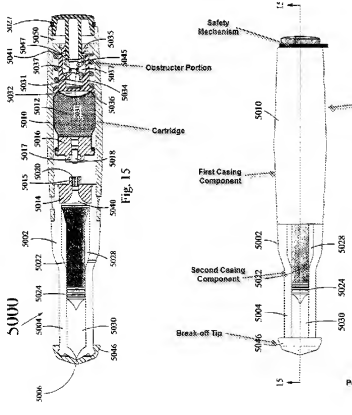

Fig. 15

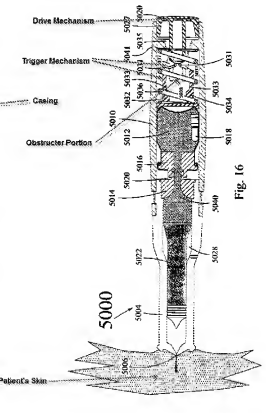

Fig. 16

3. Claims 31, and 33-56 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Pub. No. 2001/0031945 to Haar et al.

Regarding claims 31 and 33-56, Haar teaches a casing **(46)**; a cartridge **(11)** containing a medicament and an orifice at one end; a drive mechanism **(48)** which upon actuation applies force to the medicament, forcing the medicament out of the orifice and through the patient's skin; a trigger mechanism **(36)** which actuates the drive mechanism; a safety mechanism **(39)** which, in a first configuration, prevents the trigger mechanism from actuating the drive mechanism and in a second configuration allows trigger mechanism to actuate the drive mechanism **(figure 4 to figure 5)**, wherein the casing encloses injector device components and incorporates an actuator mechanism **(outside of casing 46)** which moves the safety mechanism from its first configuration into its second configuration **(figure 4 to figure 5)**; wherein the actuator mechanism comprises a portion extending outside of the casing which portion is accessible to a user and which when the portion is moved by the user the movement brings the safety mechanism into its second configuration **(figure 4 to figure 5)**; wherein the safety mechanism in its first configuration prevents the trigger mechanism from moving **(0069)**; wherein the actuator mechanism has a structure selected from the group consisting of a button, a tongue and a lever **(figures 4 and 5 show a button)**; wherein the actuator mechanism is comprised of a component which applies a pulling force to the safety mechanism to pull the safety mechanism from its first configuration into its second configuration **(a pulling force is present as implied in figures 4 and 5 on the safety mechanism)**; further comprising: a retaining mechanism **(indentations/concave depressions on push rod 38)** which retains the safety mechanism of an enclosed injection device in its second configuration after the safety mechanism has been

brought into its second configuration **(figures 4 and 5)**; wherein the safety mechanism comprises an obstructer portion which in the first configuration obstructs, and in the second configuration allows, movement of the trigger mechanism **(the balls of the ball latch act as obstructing mechanisms)**; wherein the safety mechanism comprises a collar shaped to surround a portion of the injection device, the collar is moveable from its first collar configuration into its second collar configuration in a direction generally perpendicular to a direction in which the medicament exits the orifice, the collar comprising an obstructer portion **(the balls of the ball latch act as a collar since they provide restraint)**; wherein the trigger mechanism is comprised of two moveable upper **(46 touching trigger)** and lower sleeve **(49 touching trigger)** portions which on relative movement allow the drive mechanism to act, and the safety mechanism comprises an obstructer portion which in its first configuration obstructs, and in its second configuration allows, the relative movement of the sleeve portions **(figure 4 to figure 5)**; a break-off tip **(22)** which closes the cartridge orifice prior to being broken off; wherein the casing provides for a sequential operation of the needleless injection device **(figure 4 to figure 5)**; wherein the sequential operation provides for (a) breaking off the break-off tip; and (b) placing the safety mechanism in the second position **(figure 4 to figure 5)**; wherein breaking off the break-off tip exposes an actuator for the safety mechanism **(allows for actuation thus exposing the actuator)**; wherein the casing comprises moveable first **(46)** and second **(44)** casing components, a first casing component adapted to hold the injection device, and a second casing component adapted to bear upon the break-off tip as a result of relative motion of the first and second components to apply a force thereto causing the break-off tip to break off from an injection device enclosed within the casing **(figure 4 to figure 5)**; wherein the first casing

component is elongated with an opening at a first end **(figure 4)**; wherein the first casing component is elongated along a longitudinal axis, and wherein the second casing component is designed to apply a rotary motion relative to the first portion so as to bear on the break-off tip of a container held by the first casing portion, and to apply a twisting shearing force to the frangible joint between the break-off tip and the container **(capability shown in figure 4)**; wherein the rotary motion is chosen from: transverse to the longitudinal axis; perpendicular to the longitudinal axis; coaxial with the longitudinal axis; about a rotation axis parallel to but non-coaxial with the longitudinal axis; about a rotation axis at a non-zero angle to the longitudinal axis **(capability shown in figure 4)**; wherein the rotary motion is about a rotation axis at a non-zero angle to the longitudinal axis **(capability shown in figure 4)**; wherein the second casing component comprises a cover portion over the actuator for the safety mechanism which prevents operation of the actuator for the safety mechanism until the cover portion is removed **(figure 4 to figure 5)**; wherein the actuator for the safety mechanism moves the safety mechanism from its first configuration to its second configuration **(figure 4 to figure 5)**; wherein the drive mechanism comprises a compressed gas cylinder **(11)**; wherein the casing comprises a first casing sub-part and a second casing sub-part which fit together by a method chosen from, a tight friction fit, and a snap-fit fit **(both appear to be shown in figure 4)**; a first break away part **(outside of trigger, figure 4)** and a second break away part **(22)**.

Response to Arguments

4. Applicant's arguments filed 11/02/2009 have been fully considered but they are not persuasive.

Regarding the Applicant's arguments regarding the Castellano prior art reference, the Examiner would like to remind the Applicant that the claims must be "given their broadest reasonable interpretation consistent with the specification" **(MPEP 2111)**. Regarding the imported limitation which was previously claim 32, Castellano does teach this within the broadest reasonable interpretation (i.e. via the biasing member 5041 the actuator button may be in a first configuration in which the safety clip is not directly abutting the distal end of the needleless injector, upon downward movement or depression of the actuator button 5029 the safety clip abuts the distal end of the actuator button thus preventing further depression and arriving at a second configuration, note that the first and second configurations may be transposed, and note that these configurations may exist at points which are separated by an infinitesimal distance since the claims do not specify the location or distance in relative terms with respect to the configurations). The Examiner asserts that this limitation is constructed too broadly and suggests narrowing the limitation by further describing the nature of the two configurations so as to obviate the prior art reference of Castellano. Regarding claims 41 and 56, the Examiner reads the limitation "break-off tip" as a very broad limitation. In this essence, the Examiner asserts that the protective cap 5046 of Castellano may be "broken-off" as a matter of intended use.

Regarding the Applicant's arguments regarding the Haar prior art reference, the Examiner asserts that each and every limitation is taught within broadest reasonable interpretation and this is shown clearly in the above office action. Figure 4 to figure 5 show two different configurations, and a latch may be construed as a safety mechanism. The Examiner further asserts that tip 22 may be "broken-off".

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GERALD LANDRY II whose telephone number is (571)270-7409. The examiner can normally be reached on M-F, 7:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GEL/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763